UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,982	06/15/2006	Robert C. Shipman	13516-4	1560

1059 7590 07/20/2007

BERESKIN AND PARR
40 KING STREET WEST
BOX 401
TORONTO, ON M5H 3Y2
CANADA

EXAMINER	
POHNERT, STEVEN C	
ART UNIT	**PAPER NUMBER**
1634	

MAIL DATE	DELIVERY MODE
07/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,982	SHIPMAN ET AL.	
	Examiner	Art Unit	
	Steven C. Pohnert	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-77* is/are pending in the application.

4a) Of the above claim(s) *51-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-50 and 71-77* is/are rejected.

7)☒ Claim(s) *49 and 75* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/27/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 47-50 and 71-77 and SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44, 70, 71, 76, 77, 88-99, 116, 117, 134 and 135 in the reply filed on 5/16/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 51-70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/16/2007.

Specification

2. The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

An example of an embedded hyperlink is page 1, line18. Applicant is required to check the rest of the document for embedded hyperlinks and delete them.

Appropriate correction is required.

Claim Objections

3. Claims 49 and 75 are objected to because of the following informalities: The claim refers to figures or tables. MPEP 2173.05(s) states:

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is

no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 47-50, 71-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims 47-50 and 71-77 encompass two or more nucleic acid or two or more primer pairs molecules that hybridize to "any" ATP-Binding cassette transporter gene. Claim 48 draws the invention to the 3' untranslated region, while claim the election response draws claims 49 and 73 to nucleic acids that are homologous, complementary, or fragments of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44. Claim 75 draws the claims to primer pairs of SEQ ID NO 70, 71, 76, 77, 88-99, 116, 117, 134 and 135. The claims do not set forth any structural requirements for an ABC transporter gene, other than the recited SEQ ID NO.

When the claims are analyzed in light of the specification, the invention encompasses an enormous number of nucleotide molecules. The specification teaches, " ABC transporters genes in this application are intended to include unknown transporter genes, which will be discover or confirmed in the future" (see page 11, last paragraph to top page 11). The specification further teaches that human ABC transporters are examples of ABC transporter genes. Thus the specification teaches ABC transporter genes are from "any" species. The specification further teaches homology refers to a degree of complementary and includes partially complementary (see page 13, lines 11-15). The specification further teaches partial complementary includes less than about 30% identity (see page 13, line 27). Thus the specification teaches homology includes less than about 30% identity. The claims read in light of the specification encompass an enormous genus of nucleic acids broadly encompassed by ABC transporter genes in "any" species. This large genus of ABC transporters broadly encompasses "any" nucleic acid that is about 30% or more identical to "any" ABC transporter gene or the recited SEQ ID NO. This genus further increases exponentially as the claims are drawn to "any" nucleic acid or primer pairs that are about 30% identical to "any" ABC transporter gene or a fragment. The claims thus encompass any primer pairs or nucleic acid or fragment that has 30% identity with any ABC transporter gene or its complement. This is an enormous genus of nucleic acids. The specification further specifically teaches they are claiming sequences that are unknown.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been disclosed.

The instant specification teaches SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 and SEQ ID NO 70, 71, 76, 77, 88-99, 116, 117, 134 and 135 sequences. The specification does not teach "any" sequences that are 30% identical to the recited SEQ ID NO's or fragments other than the primers taught in Table 1. The specification thus teaches 141 human sequences, which is not representative of the 100s of thousands of sequences claimed by ABC transporter genes and their fragments and complements. Further the specification does not teach how to identify the unknown ABC gene transporter sequences claimed.

Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. other nucleotide sequences or positions with in a specific gene or nucleic acid), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case the specification provides no structural limitations. The claims read in light of the specification encompass any nucleic acid molecule or fragment that is complementary to "any" ABC transporter gene in "any" species or "any" nucleic acid that has 30% identity to an ABC transporter gene, SEQ ID NO or fragment. This is an enormous genus of nucleic acids.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The

specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acids regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. The current situation is a definition of the compound solely based on its functional utility, as a polymorphism, without any definition of the particular polymorphisms claimed.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

In the instant application, the provided information regarding nucleic acid ATP-binding cassette transporter fragments, homologs and genes, do not constitute an adequate written description of the broad subject matter of the claims, so one of skill in

the art cannot envision the detailed chemical structure of the nucleic acids encompassed by nucleic acids. Adequate written description requires more than a statement that nucleic acids with a particular quality are part of the invention and reference to a potential method for their identification. The nucleic acid sequence is required.

In conclusion, the limited information provided regarding ATP-binding cassette transporter fragments, homologs and genes is not deemed sufficient to reasonably convey to one skilled in the art nucleic acid molecules encompassed by fragments, homologs and genes "any" ATP binding cassette of "any" species.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 47-50 an d71-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 47-50 and 71-77 recite, "Two or more isolated nucleic acid molecules, wherein each of the nucleic acid molecules comprises a sequence that hybridizes to one ATP-binding cassette (ABC) transporter gene." It is unclear if the claim is drawn to two isolated nucleic acid molecules that hybridize to a single ABC transporter gene or if

the claim is drawn to two isolated nucleic acid molecules that each target a separate ABC transporter gene.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 47-50 and 71-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Denefle et al (WO02/46458, published June 13, 2002).

The instant claims are drawn two or more nucleic acid. However, it does not require these nucleic acids are different.

With regards to claim 47, Denefle et al teaches a detection of ABCA genes by the use of a plurality of primers or probes immobilized on a solid support (see page 68, lines 20-25). Denefle thus teaches an array of nucleic acids molecules immobilized on a solid support.

With regards to claim 48, Denefle et al teaches the use of SEQ ID No 1-4 and fragments thereof as probes (see page 68, line 6). Denefle et al further teaches SEQ ID NO 1 comprises the coding sequence of ABCA5 with the start codon at position 1011. Denefle et al thus teaches an array with two or more nucleic acids comprising a portion of the 3' untranslated region.

Claim 49 is drawn to an array containing two or more of the nucleic acids of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 or complements or homologs or fragments.

The specification teaches homologous probes can have 30% identity. Further, the specification suggests complementary is capable of base pairing, thus the claims broadly encompass any nucleic acid or fragment with 2 bp that can base pair (see page 14, lines 23-25).

With regards to claim 49, Denefle teaches SEQ ID No 1-4 and 9-126. Denefle thus anticipates the claims as he teaches sequence or fragments that can base pair with at least 2 nucleotides of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, and 44.

The specification teaches a DNA microarray refers to a substrate with at least one target nucleic acid immobilized.

With regards to claim 50, Denefle teaches of probes attached to a solid support. The solid support of Denefle is a substrate with at least one target nucleic acid immobilized. Denefle thus anticipates claim 50.

With regards to claim 71, Denefle et al teaches SEQ ID No 1-4 and 9-126 for detection of ABC transporter genes (see page 68, line 6). Denefle et al thus teaches two or more nucleic acid sequences comprising a sequence that hybridizes to an ABC transporter gene.

With regards to claim 72, Denefle et al teaches the use of SEQ ID No 1-4 and fragments thereof as probes (see page 68, line 6). Denefle et al further teaches SEQ ID NO 1 comprises the coding sequence of ABCA5 with the start codon at position 1011. Denefle et al thus teaches an array with two or more nucleic acids comprising a portion of the 3' untranslated region.

Claim 73 is drawn to an array containing two or more of the nucleic acids of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 or complements or homologs or fragments. The specification teaches homologous probes can have 30% identity. Further, the specification suggests complementary is capable of base pairing, thus the claims broadly encompass any nucleic acid or fragment with 2 bp that can base pair (see page 14, lines 23-25).

With regards to claim 73, Denefle teaches SEQ ID No 1-4 and 9-126. Denefle thus anticipates the claims as he teaches sequence or fragments that can base pair with at least 2 nucleotides of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, and 44.

With regards to claim 74, Denefle et al teaches 40 primer pairs primers in tables 11-14. These primers are directed to genes of the ABC transporter family and thus would amplify homologous ABC transporter gene fragments or complements, which as defined by the specification is 30% identity. Denefle thus anticipates 2 or more primer pairs that have at least 30% identity with SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44.

With regards to claim 75 and 76, Denefle et al teaches 40 primer pairs primers in tables 11-14. These primers are directed to genes of the ABC transporter family and thus would include primers that are complements or homologous to SEQ ID NO 70, 71, 76, 77, 88-99, 116, 117, 134 and 135, which as defined by the specification is 30% identity. Denefle thus anticipates 2 or more primer pairs that have at least 30% identity with SEQ ID NO 70, 71, 76, 77, 88-99, 116, 117, 134 and 135.

The MPEP states in 2113, ""[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

With regards to claim 77, Denefle teaches amplification of a target nucleic acid by the use of primer pairs and an amplification (see page 69, lines 19-24). Denefle further teaches detection of the amplification product. Denefle thus teaches the isolated nucleic acids prepared by using PCR and the primer pairs.

10. Claims 47-50 and 71-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5474796, issue December 12, 1995).

With regards to claim 47, Brennan teaches an array of all possible 10mer oligonucleotides (see column 9 rows 48-67). Brennan teaches the array is a glass plate to which the oligonucleotides are immobilized (see column 7, lines 21-25). The array of Brennan comprising all 10mer oligonucleotides would set forth two or nucleic acid molecules comprising a sequence that hybridizes to one ATP-binding cassette gene. Teachings of Brennan would thus anticipate Claim 47.

With regards to claim 48, Brennan teaches an array of all possible 10mer oligonucleotides (see column 9 rows 48-67). The array of Brennan comprising all 10mer oligonucleotides would set forth two or nucleic acid molecules comprising a

sequence that hybridizes to the 3' untranslated region of ATP-binding cassette gene. Teachings of Brennan would thus anticipate Claim 48, as it comprises all possible 10mers.

Claim 49 is drawn to an array containing two or more of the nucleic acids of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 or complements or homologs or fragments. The specification teaches homologous probes can have 30% identity. Further, the specification suggests complementary is capable of base pairing, thus the claims read on any nucleic acid or fragment with 2 bp that can base pair(see page 14, lines 23-25).

With regards to claim 49, Brennan teaches an array of all possible 10mer oligonucleotides (see column 9 rows 48-67). The array of Brennan comprising all 10mer oligonucleotides would set forth two or nucleic acid molecules comprising a sequence or fragments that can base pair with at least 2 nucleotides of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 of ATP-binding cassette gene. Teachings of Brennan would thus anticipate Claim 49.

The specification teaches a DNA microarray refers to a substrate with at least one target nucleic acid immobilized.

With regards to claim 50, Brennan teaches the array is a glass plate to which the oligonucleotides are immobilized (see column 7, lines 21-25). Brennan thus anticipates claim 50.

With regards to claim 71, Brennan teaches an array of all possible 10mer oligonucleotides (see column 9 rows 48-67). The array of Brennan comprising all

10mer oligonucleotides would set forth two or nucleic acid molecules comprising a sequence or fragments that can base pair with at least 2 nucleotides of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 of ATP-binding cassette gene. Teachings of Brennan would thus anticipate Claim 49.

With regards to claim 72, Brennan teaches an array of all possible 10mer oligonucleotides (see column 9 rows 48-67). The array of Brennan comprising all 10mer oligonucleotides would set forth two or nucleic acid molecules comprising a sequence that hybridizes to one ATP-binding cassette gene. Teachings of Brennan would thus anticipate Claim 47.

With regards to claim 73, Brennan teaches an array of all possible 10mer oligonucleotides (see column 9 rows 48-67). The array of Brennan comprising all 10mer oligonucleotides would set forth two or nucleic acid molecules comprising a sequence that hybridizes to the 3' untranslated region of ATP-binding cassette gene, as Brennan teaches all possible 10mers. Teachings of Brennan would thus anticipate Claim 73.

Claim 74 is drawn to two or more pairs of primers. The specification teaches a " 'pair(s) of primers' refers to an upper primer and a lower primer" (see page 13, lines 6). Thus a primer pair reads on "any" two nucleic acids that hybridize to nucleic acid sequence.

With regards to claim 74, Brennan teaches an array of all possible 10mer oligonucleotides (see column 9 rows 48-67). The array of Brennan comprising all 10mer oligonucleotides would set forth two or more primer pairs for an ATP-binding

cassette gene. Teachings of Brennan would thus anticipate Claim 74.

Claim 75 is drawn to an array containing two or more primer pairs of SEQ ID NO 70, 71, 76, 77, 88-99, 116, 117, 134 and 135 or complements or homologs or fragments. The specification teaches homologous probes can have 30% identity. Further, the specification suggests complementary is capable of base pairing, thus the claims read on any nucleic acid or fragment with 2 bp that can base pair(see page 14, lines 23-25).

With regards to claim 75 and 76, Brennan teaches an array of all possible 10mer oligonucleotides (see column 9 rows 48-67). The array of Brennan comprising all 10mer oligonucleotides would set forth two or more primer pairs for an ATP-binding cassette gene. These 10mers of Brennan encompass all 10mers and thus would include primers that are complements or homologous to SEQ ID NO 70, 71, 76, 77, 88-99, 116, 117, 134 and 135 (homology as defined by the specification is 30% identity).

The MPEP states in 2113, ""[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Claim 77 thus requires isolated nucleic acids of claim 76 and is thus anticipated by Brennan.

Summary

No claims are allowed over prior art cited.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

/Carla Myers/
Primary Examiner, Art Unit 1634